

ATTORNEY DOCKET NO. 2001796-0008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: A. John Bramley
Serial No.: 10/087,667
Filing Date: February 28, 2002
Title: TREATMENT OF STAPHYLOCOCCUS INFECTIONS

Examiner:
Art Unit: 1632

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, DC 20231

Sir:

STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE
UNDER 37 CFR §§1.56, 1.97 AND 1.98

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants respectfully request consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

(Select A, B or C below)

- A. ☒ This Information Disclosure Statement has been filed:
(check 1, 2 and/or 3 below)
1. ☐ within three months of the filing date of the above identified U.S. Patent application;
 2. ☐ within three months of the filing date of the entry of the National Stage, as set forth in 37 C.F.R. §1.491, in an International application; and/or
 3. ☒ before the mailing date of the first Office Action on the merits in the above-identified application.

No fee or certification is required.

- B. ☐ This Information Disclosure Statement has been filed more than three months after the filing date of the present application and after the mailing date of this

first Office Action, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311.

(check 1 or 2 below)

1. ☐ The fee of \$180 as set forth in 37 C.F.R. §1.17(p) is enclosed; or
2. ☐ Applicants hereby certify, as specified in 37 C.F.R. §1.97(e), that
(check a or b below)
 - a. ☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign Patent Office in a counterpart for this application not more than three months prior to the filing of this Statement; or
 - b. ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign Patent Office in a counterpart for this application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Statement.
 - c. ☒ items indicated by an asterisk were identified in a recent review of related files.

- C. ☐ This Information Disclosure Statement has been filed after the mailing date of either a Final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311 and before payment of an Issue Fee.

(check 1, 2, and 3 below)

1. ☐ The Applicant hereby certifies, as specified in 37 C.F.R. §1.97(e), that:
(check a or b below)
 - a. ☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign Patent Office in a counterpart for this application not more than three months prior to the filing of this Statement.

- b. ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign Patent Office in a counterpart for this application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Statement.
2. ☐ A Petition requesting consideration of the Information Disclosure Statement is attached.
3. ☐ The Petition Fee of \$130 as set forth in 37 C.F.R. §1.17(i)(1) is enclosed.

PART II - Information Cited

- A. ☒ The Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.
- B. ☐ The Applicant hereby makes the following additional information of record in the above-identified application:

PART III: Explanation of Non-English Language References and Remarks Concerning Other Information Cited

- A. ☐ The following is a concise explanation of the relevance of each non-English language reference listed on the attached form PTO-1449 (modified):
- B. ☐ The following are remarks concerning the other information cited:

PART IV: Remarks

- A. ☒ Copies of references
(check 1 or 2 below)

1. ☐ A copy of each of the references cited on the attached form PTO-1449 (modified) is enclosed;
 2. ☒ Copies of certain of the references cited on the attached form PTO-1449 (modified) are not enclosed because each of these references (indicated by asterisk) was previously cited by or submitted to the Office in a prior application, U.S.S.N. 09/337,079 , which prior application is relied upon for an earlier filing date under 35 U.S.C. § 120.
- B. ☒ It is respectfully requested that:
(check 1, 2, and 3 below)
1. ☒ The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
 2. ☒ The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application;
 3. ☒ The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.
- C. ☒ By submitting this Information Disclosure Statement, Applicants make no representation that a search has been performed, of the extent of any search performed, or that more material information may not exist.
- D. ☒ By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).


- E. [X] By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.
- F. [X] Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

An early and favorable action is hereby requested.

Please charge any additional fees or credit any overpayments to our Deposit Account No. 03-1721.

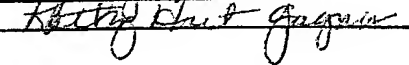
Respectfully submitted,

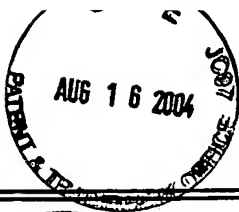
By:


Brenda Herschbach Jarrell
Registration Number 39,223

CHOATE, HALL & STEWART
Exchange Place
53 State Street
Boston, Massachusetts 02109
(617) 248-5000
Dated: July 2, 2002

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner For Patents, Washington, D.C. 20231 on July 3, 2002





Applicants Copy #8

Form PTO-1449

(REV. 8-83)

AUG 11 2000

U.S. Department of
Commerce
Patent and
Trademark Office

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket:
2001796-0005

In re Application No.
09/337,079

Applicants: Bramley, et al.

Filing Date: June 21, 1999

Group:

U. S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
qw	4,931,390	Recsei	June 5, 1990	435	183
qw	5,011,772	Recsei	April 30, 1991	435	69.1
qw	5,124,145	Sordillo et al.	June 23, 1992	424	85.5
qw	5,189,015	Höök et al	February 23, 1993	514	2
qw	5,234,684	Sordillo et al.	August 10, 1993	424	85.5
qw	5,342,612	Daley et al.	August 30, 1994	424	85.1
qw	5,607,919	Bojsen et al.	March 4, 1997	514	12
qw	6,028,051	Climo et al.	February 22, 2000	514	2

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No
qw	WO 87/06264	International	22 October 1987	X	
qw	WO 96/35793	International	14 November 1996	X	
qw	WO 99/05289	International	4 February 1999	X	
qw	EP 0 359 873	Europe	19 September 1988	X	
qw	EP 0 759 473	Europe	23 August 1995	X	

Examiner's
Initials

OTHER DOCUMENTS
(Including Author, Title, Date, Pertinent Pages, Etc.)

Joe Wontach 1/8/01

Form PTO-1449

(REV. 8-83)

U.S. Department of
Commerce
Patent and
Trademark Office

Atty. Docket:
2001796-0005

In re Application No.
09/337,079

Applicants: Bramley, et al.

Filing Date: June 21, 1999

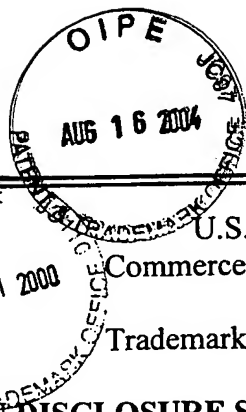
Group:

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

9w	Archer, et al., "Human Growth Hormone (hGH) Secretion in Milk of Goats After Direct Transfer of the hGH Gene into the Mammary Gland by Using Replication-Defective Retrovirus Vectors", <i>Proc. Natl. Acad. Sci.</i> 91:6840-44, July 1994.
9w	Auldist, et al., "Changes in the Composition of Milk from Healthy and Mastitic Dairy Cows During the Lactation Cycle", <i>Aust. J. Exp. Agricul.</i> 35: 427-36, 1995.
9w	Auldist, et al., "Effect of Somatic Cell Count and Stage of Lactation on the Quality and Storage Life of Ultra High Temperature Milk", <i>J. Dairy Res.</i> 63: 377-386, 1996.
9w	Barbano, et al., "Influence of Milk Somatic Cell Count and Milk Age on Cheese Yield", <i>J. Dairy Sci.</i> 74: 369-88, 1991.
9w	Bramley, et al., "Effects of Lysostaphin on Staphylococcus Aureus Infections of the Mouse Mammary Gland", <i>Research in Veterinary Science</i> , 49: 120-21; 1990.
9w	Bramley, et al., "Reviews of the Progress of Dairy Science: Mastitis Control - Progress and Prospects" <i>Journal of Dairy Research</i> , 51, 481-512, 1984.
9w	Chandler, R.L., "Experimental Bacterial Mastitis in the Mouse", <i>J. Med. Microbiol.</i> 3: 273-82, 1970.
note supplied	Chomczynski, et al., "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction", <i>Anal. Biochem.</i> 162: 156-59, 1987.
9w	Craven, et al., "Phagocytosis of Staphylococcus Aureus by Bovine Mammary Gland Macrophages and Intracellular Protection from Antibiotic Action in Vitor and In Vivo", <i>J. Dairy Res.</i> 51: 513-23, 1984.
9w	Craven, et al., "Antibiotic Activity Against Intraleukocytic Staphylococcus Aureus in Vitro and In Experimental Mastitis in Mice", <i>Am. J. Vet. Res.</i> 44:(4), 709-12, 1983.
9w	Daley, et al., "Lysostaphin: Immunogenicity of Locally Administered Recombinant Protein Used in Mastitis Therapy", <i>Veterinary Immunology and Immunopathology</i> , 31: 301-12, 1992.

Joe Wintable 1/8/01



Form PTO-1449

(REV. 8-83)

U.S. Department of
CommercePatent and
Trademark Office

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket:
2001796-0005In re Application No.
09/337,079

Applicants: Bramley, et al.

Filing Date: June 21, 1999

Group:

qw

Derbyshire, et al., "Immunization Against Experimental Staphylococcal Mastitis in the Goat by the Intramammary Infusion of Cell-Toxoid Vaccine" *Res. Vet. Sci.*, 10:559-64, 1969.

qw

Ebert, et al., "Transgenic Production of a Variant of Human Tissue-Type Plasminogen Activator in Goat Milk: Generation of Transgenic Goats and Analysis of Expression", *Bio/Technology*, 9: 835-38, 1991.

qw

Gordon, et al., "Production of Human Tissue Plasminogen Activator in Transgenic Mouse Milk", *Bio/Technology*, 5: 1183-87, 1987.

qw

Harmon, et al., "Concentration of Lactoferrin in Milk of Normal Lactating Cows and Changes Occurring during Mastitis" *Am. J. Vet. Res.* 36: 1001-1007, 1975.

qw

Heinrich, et al., "The Molecular Organization of the Lysostaphin Gene and its Sequences Repeated in Tandem", *Mol. Gen Genet*, 209:563-69, 1987.

qw

Jacob, et al., "Potential Therapeutic Applications of Magainins and Other Antimicrobial Agents of Animal Origin", *Ciba. Found. Symp.* 186 : 197-216, discussion, 216-23, 1994.

qw

Kagan, et al., "Defensins: A Family of Antimicrobial and Cytotoxic Peptides", *Toxicology*, 87: 131-49, 1994.

qw

Kerr, et al., "Expression of Jet-Injected Plasmid DNA in the Ovine Mammary Gland and In Lymph Nodes Draining the Injection Site", **NOT MUCH HERE.**

qw

Klei, et al., "Effects of Milk Somatic Cell Count on Cottage Cheese Yield and Quality", *J. Dairy Sci.* 81:1205-13, 1998.

qw

Kossaibati, et al., "Incidence of Clinical Mastitis in Dairy Herds in England", *Vet. Rec.* 143:649-53, 1998.

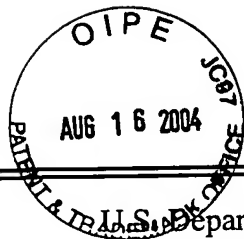
qw

Krimpenfort, et a., "Generation of Transgenic Dairy Cattle Using 'In Vitro' Embryo Production" *Bio/Technology*, 9: 844-47, 1991.

Joe Wintach 11/8/01

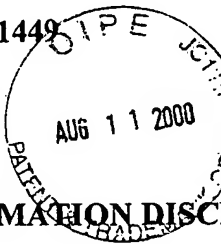
Form PTO-1449 (REV. 8-83)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket: 2001796-0005	In re Application No. 09/337,079
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicants: Bramley, et al.	
		Filing Date: June 21, 1999	Group:
gw	Liang, et al., "Molecular Cloning and Nucleotide Sequence of the β -Lytic Protease Gene from <i>Achromobacter Lyticus</i> " <i>Journal of Bacteriology</i> , 172(11): 6506-11; 1990.		
gw	Maga, et al., "Antimicrobial Properties of Human Lysozyme Transgenic Mouse Milk", <i>J. Food Prot.</i> 61: 52-56, 1998.		
gw	Maga, et al., "The Effect of Mammary Gland Expression of Human Lysozyme on the Properties of Milk From Transgenic Mice", <i>J. Dairy Sci.</i> 78: 2645-52, 1995.		
gw	Myllys, et al., "Bovine Mastitis in Finland in 1988 and 1995--Changes in Prevalence and Antimicrobial Resistance", <i>Acta Vet. Scand.</i> 39: 119-126, 1998.		
gw	Nickerson, et al., "Symposium: Mastitis in Dairy Heifers, Mastitis in Dairy Heifers: Initial Studies on Prevalence and Control", <i>J Dairy Sci</i> , 78: 1607-18, 1995.		
gw	Nuijens, et al., "Characterization of Recombinant Human Lactoferrin Secreted in Milk of Transgenic Mice" <i>The Journal of Biological Chemistry</i> , 272 (13): 8802-07, 1997.		
gw	Oldham, et al., "Lysostaphin: Use of a Recombinant Bactericidal Enzyme as a Mastitis Therapeutic", <i>J. Dairy Sci.</i> , 74: 4175-82, 1991.		
gw	Platenburg, et al., "Expression of Human Lactoferrin Milk of Transgenic Mice", <i>Transgenic Res.</i> 3: 99-108, 1994.		
gw	Plaut, et al., "Integration of the lacZ Gene into the Mammary Gland Using an Adenovirus Vector", <i>Journal of Dairy Science</i> , 80:1, 1997.		
gw	Recsei, et al., "Cloning, Sequence, and Expression of the Lysostaphin Gene From <i>Staphylococcus Simulans</i> ", <i>Proc. Natl. Acad. Sci., USA</i> , 84: 1127-31, 1987.		
gw	Reiter, B., "Review of the Progress of Dairy Science: Antimicrobial Systems in Milk", <i>J. Dairy Res.</i> 45: 131-47, 1978.		
gw	Sambrook, et al., "Expression of Cloned Genes in Cultured Mammalian Cells", NOT MUCH HERE. Book 3 Chapter 16 pp 16.1-16.81		

Joe Wontade 1/8/01



Form PTO-1449

(REV. 8-83)

U.S. Department of
Commerce
Patent and
Trademark Office

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket:
2001796-0005In re Application No.
09/337,079

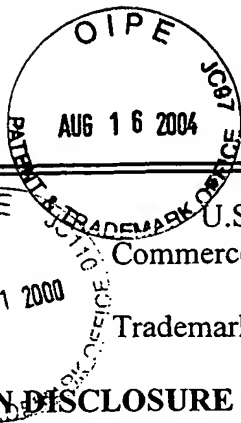
Applicants: Bramley, et al.

Filing Date: June 21, 1999

Group:

9w	Schindler, et al., "Lysostaphin: A New Bacteriolytic Agent For the <i>Staphylococcus</i> . <i>Proc. Natl. Acad. Sci. U.S.A.</i> 51: 414-421, 1964.
9w	Schnieke, et al., "Human Factor IX Transgenic Sheep Produced by Transfer of Nuclei From Transfected Fetal Fibroblasts", <i>Science</i> , 278: 2130-33, 1997.
9w	Shockman, et al., "Structure, Function, and Assembly of Cell Walls of Gram-Positive Bacteria", <i>Annu. Rev. Microbiol.</i> 37: 501-27, 1983.
9w	Sutra, et al., "Virulence Factors Involved in the Pathogenesis of Bovine Intramammary Infections Due to <i>Staphylococcus Aureus</i> ", <i>J. Med. Microbiol.</i> 40: 79-89, 1994.
9w	Takahashi, et al., "Nonspecific Antibacterial Factors in Milk from Cows Immunized with Human Oral Bacterial Pathogens", <i>J. Dairy Sci.</i> 75: 1810-20, 1992.
9w	Thumm, et al., "Studies on Prolysostaphin Processing and Characterization of the Lysostaphin Immunity Factor (Lif) of <i>Staphylococcus Simulans</i> Biovar <i>Staphylolyticus</i> " <i>Molecular Microbiology</i> , 23(6), 1251-65, 1997.
9w	Verdi, et al., "Variability in True Protein, Casein, Nonprotein Nitrogen, and Proteolysis in High and Low Somatic Cell Milks", <i>J. Dairy Sci.</i> 70: 230-42, 1987.
9w	Wall, et al., "High-Level Synthesis of a Heterologous Milk Protein in the Mammary Glands of Transgenic Swine", <i>Proc. Natl. Acad Sci USA</i> , 88: 1696-1700, 1991.
9w	Watson, et al., "A Field Trial to Test the Efficacy of a Staphylococcal Mastitis Vaccine in Commercial Dairies in Australia",
9w	Williamson, et al., "Expression of Lysostaphin in the Milk of Transgenic Animals to Combat Staphylococcal Mastitis", <i>J. Appl Bacteriol.</i> 67:6, xxi, 1986.
9w	Williamson, et al., "Expression of the Lysostaphin Gene of <i>Staphylococcus Simulans</i> in a Eukaryotic System", <i>Applied and Environment Microbiology</i> , 60:3, 771-76, March, 1994.

Joe Wontach 1/8/01



Form PTO-1449 (REV. 8-83) U.S. Department of Commerce Patent and Trademark Office

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket:
2001796-0005

In re Application No.
09/337,079

Applicants: Bramley, et al.

Filing Date: June 21, 1999

Group:

qW

Wilson, et al., "Bovine Mastitis Pathogens in New York an Pennsylvania: Prevalence and Effects on Somatic Cell Count and Milk Production", *J. Dairy Sci.* **80**: 2592-98, 1997.

qW

Wright, et al., "High Level Expression of Active Human Alpha-1-Antitrypsin in the Milk of Transgenic Sheep", *Bio/Technology*, **9**:830-34, 1991.

qW

Yamada, et al., "An Autolysin Ring Associated with Cell Separation of Staphylococcus Aureus", *J. Bacterial.* **178**: 1565-71, 1996.

qW

Yancey, et al., "Activity of Antibiotics Against Staphylococcus Aureus Within Polymorphonuclear Neutrophils", *Eur. J. Clin. Microbiol. Infect. Dis.* **10**:107-113, 1991.

qW

Yarus, et al., "Production of Active Bovine Trachael Antimicrobial Peptide in Milk of Transgenic Mice", *Proc. Natl. Acad. Sci. USA*, **93**, 14118-21, November, 1996.

qW

Zavizion, et al., "Effects of Staphylococcus Aureus Toxins on the Growth of Bovine Mammary Epithelial Cells (MAC-T) in Culture", *J. Dairy Sci.*, **78**, 277-84, 1995.

EXAMINER

Joe W. W. W.

DATE CONSIDERED

1/8/01

50

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.